REMARKS

Claims 1-10 are pending in the instant application. Claim 1-10 have been rejected. Claims 1 and 4 have been amended, as supported throughout the specification and at page 8, line 18. No new matter is added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claim 4 under 35 U.S.C. § 112

The Examiner has rejected claim 4 under 35 U.S.C. § 112 first paragraph. The Examiner suggests that the specification while being enabling for acetone does not reasonably provide enablement for all organic solvents. The Examiner suggests that acetone is the only organic solvent that is disclosed in the specification and that it would require a skilled artisian an unreasonable amount of experimentation to ascertain those solvents which are suitable for the haloperidol-lactide-glycolide system. The Examiner further suggests that the specification provides guidance only to acetone as the organic solvent and that the specification is lacking information on how the haloperidol-lactide glycolide system will behave in organic solvents other than acetone. The Examiner suggests that the scope of the claims

is not commensurate with the disclosure because the specification enables acetone as the solvent and does not provide direction as to other solvents.

Applicants respectfully disagree with this rejection.

As set forth in the MPEP at 2164.01(a), There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The Court has previously held that there is not considered undue experimentation to identify suitable components needed to practice the claimed method when there is a high level of skill in the art, see *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface

antigens did not satisfy the enablement requirement). *In re Wands,* 858 F.2d at 736-40, 8 USPQ2d at 1403-07. The Court held that the specification was enabling with respect to the claims at issue and found that "there was considerable direction and guidance" in the specification; there was "a high level of skill in the art at the time the application was filed;" and "all of the methods needed to practice the invention were well known." 858 F.2d at 740, 8 USPQ2d at 1406. After considering all the factors related to the enablement issue, the court concluded that "it would not require undue experimentation to obtain antibodies needed to practice the claimed invention." *Id.*, 8 USPQ2d at 1407.

In a like manner, Applicants believe that the Examiner has improperly concluded that the present disclosure is not enabling based on an analysis of only a portion of the above factors while ignoring one or more of the others. MPEP §2164.01(a) is clear that the examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407.

Applicants respectfully submit that claim 4 requires dissolving haloperidol and a biodegradable polymer in an organic

solvent. While acetone is an organic solvent, one of skill in the art of biodegradable polymers would understand the nature of the invention and be routinely able to ascertain suitable organic solvents in which to dissolve haloperidol and a biodegradable polymer. Applicants believe that a skilled artisian would not need an unreasonable amount of experimentation to ascertain those solvents which are suitable for dissolving haloperidol and a biodegradable polymer in an organic solvent as set forth in claim 4.

Reconsideration and withdrawal of this rejection is therefore respectfully requested.

II. Rejection of Claim 1 and 2 under 35 U.S.C. § 102(b)

Claims 1 and 2 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Kino et al. The Examiner suggests that Kino et al. discloses an implantable system that comprises haloperidol and lactic acid/glycolic acid copolymer.

Applicants respectfully traverse this rejection. Kino et al. teach a depot formulation of an antipsychotic drug containing sustained release microspheres suitable for use as a sustained release injection preparation. See for instance, column 3, at lines 49-52, column 4, at lines 59-61; and column 5, lines 10-12.

In contrast, the implant of the present invention is removable. As taught at page 8, lines 16-20, this removability offers a degree of reversibility not available with depot formulations. In an earnest effort to clarify distinctions of the present invention from depot formulations such as taught by Kino et al., claim 1 has been amended to recite that the implantable drug delivery system of the present invention is removable. Support for this amendment can be found at page 8, line 16-20.

MPEP § 2131 is clear, to anticipate a claim the reference must teach every element of the claimed invention. Since Kino et al. do not teach or suggest a is removable implant, Kino et al. cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(b) is therefore respectfully requested.

III. Rejection of Claim 1-3 under 35 U.S.C. § 102(b)

Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cheng et al. The Examiner suggests that Cheng et al. disclose a delivery system that comprises haloperidol and 50:50 lactide-glycolide copolymer in the presence of the organic solvent, dichloromethane, emulsification of the mixture and evaporated of the solvent to produce microspheres. The Examiner

suggests that haloperidol is useful in the treatment of schizophrenia, "Surgically implantable" in claim 1 is suggested to be a future intended use. Thus, Cheng is suggested to meet the limitations of claims 1-3.

Applicants respectfully disagree with this rejection.

Cheng et al. teach *in vitro* controlled release studies of haloperidol over a four to nine week period, page 211, at column 1 paragraph 2. Cheng et al. suggests that there is a possibility of providing a long-acting depot formulation for intramuscular injection once every one to four months, *Id.*

In contrast, as discussed in Section II, supra, claims 1-3 the implantable drug delivery systems of the present invention are removable and therefore offer a degree of reversibility not available with the depot formulation of Cheng et al. Applicants have amended claim 1 in accordance with teachings at page 8 to include this distinguishing feature of removability. The microphere formulation of Cheng is not removable. Thus, Cheng et al. cannot anticipate the claims of the instant application.

Withdrawal of this rejection under 35 U.S.C. § 102(b) is therefore respectfully requested.

IV. Rejection of Claim 4-10 under 35 U.S.C. § 103(a)

Claims 4-10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al., in view of Kino et al.

The Examiner has acknowledged that Cheng does not disclose formulating the haloperidol microspheres into an implant. However, the Examiner has suggested that Kino et al. disclose that a system that comprises haloperidol and lactide-glycolide copolymer is implantable. The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the haloperidol microspheres Accordingly to the teachings of Cheng et al. , with the expectation of facilitating the delivery of haloperidol with little pain.

Applicants respectfully traverse this rejection.

Claim 4 has been amended to specify that the dry haloperidol-polymer material is molded under compression into a removable surgical implant. Support for this amendment is provided at page 8, lines 16-20.

To establish a *prima facie* case of obviousness, three basic criteria must be met. MPEP 2143. First, there must be some suggestion or motivation, either in the references themselves or

in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art must teach or suggest all claim limitations.

As discussed in detail in Sections II and III, supra, formulations of Cheng and Kino are injectable depot formulations and are not removable. Thus, neither of these references, alone or in combination teach or suggest all claim limitations, namely neither teaches a surgically implantable drug delivery system which is removable. These references also fail to provide any motivation to make a surgically implantable drug delivery system which is removable as both references suggest a desire to make compositions which are useful as long-acting injectable compositions, or depot formulation. Thus, since the combination of prior art cited fails to teach or suggest all limitations of the claims as amended and fails to provide a motivation to make the present invention, the combination of cited prior art cannot render obvious the instant claimed invention.

Withdrawal of this rejection under 35 USC §103 is therefore respectfully requested.

VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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